

REMARKS

Claims 1-4, 8-11, 68, 80-83 and 86-90 were pending prior to this amendment. Claims 1 and 4 are amended herewith. Support for the claim amendments can be found, for example, on page 16, lines 27 and 28, of the specification. Claims 1-4, 8-11, 68, 80-83 and 86-90 are, therefore, currently pending with claims 1 and 4 being independent claims.

Applicant expressly reserves the right to pursue any subject matter canceled by this amendment in this or one or more continuing applications. No new matter has been added.

Finality of the Office Action

Applicant respectfully traverses the finality of this Office Action. It is stated that the previous claim amendments necessitated the new rejection under 35 U.S.C. §103. This is not accurate. The previously amended claims, claims 1, 4 and 89, were amended to limit the size of the claimed nucleic acids. If, *arguendo*, one were to agree with the new rejection, the Examiner's basis for the rejection would be applicable to the claims regardless of the size of the claimed nucleic acids and, therefore, could have been applied previously. No action on the part of the Applicant has caused this rejection to be raised, and Applicant has not been afforded an adequate opportunity to address this new rejection. Therefore, it is respectfully requested that the finality of the Office Action be withdrawn.

Rejections Under 35 U.S.C. §112

The Examiner has rejected claims 1-4, 8-11, 68, 80-83 and 86-90 under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one of ordinary skill in the art to make and/or use the invention. The rejection is based on the contention that, according to the Examiner, the application does not provide any teachings associating MIVR-1 with any function or disorder.

Applicant traverses this rejection because the Examiner has conceded a function of MIVR-1 that is sufficient to support enablement of the claimed invention, its anti-apoptotic activity, with the withdrawal of the prior utility rejection under 35 U.S.C. § 101 in view of Applicant's assertion of such activity. Applicant also notes that no evidence has been provided that establishes a reasonable basis to doubt Applicant's teachings regarding the anti-apoptotic activity of MIVR-1. The specification, therefore, clearly provides undeniably enabled uses of

the compositions of the rejected claims based on this recognized activity alone. For instance, the compositions of the rejected claims can be used to inhibit cardiac cell-death and/or to assess apoptotic levels of cardiac cells. In addition, the compositions of the rejected claims can be used in the diagnosis and treatment of conditions associated with apoptosis. Such conditions include, as has been stated previously, cardiac conditions, such as myocardial infarction, stroke, arteriosclerosis and heart failure. Therefore, the specification not only provides a recognized function associated with MIVR-1 but also teaches that MIVR-1 can be used to diagnose and/or treat specific conditions (See, e.g., page 2, lines 7-10). The present invention thus, at the very minimum, involves therapeutics, diagnostics, compositions and tools related to the anti-apoptotic activity of MIVR-1.

Therefore, based on the uses described above and provided in the instant specification, one of ordinary skill in the art is enabled to use the compositions of the rejected claims. Furthermore, as Applicant has previously argued, one of ordinary skill in the art is also enabled to make the compositions of the claims. Applicant notes that the Examiner has not contended that the compositions of the claims cannot be made with the guidance provided in the instant specification and routine experimentation in the relevant art.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §102

The Examiner has rejected claims 1, 4, 68, 81, 88 and 89 under 35 U.S.C. §102(b) as being anticipated by Xu et al., *Genomics* 2000. 66: 257-63.

Without conceding the correctness of the Examiner's rejection, Applicant has amended claims 1 and 4 such that part (a) of both of these claims require that the nucleic acid molecules be at least 23 nucleotides in length.

Accordingly, withdrawal of this rejection is respectfully requested.

Rejections Under 35 U.S.C. §103

The Examiner has rejected claims 1, 4, 68, 81, 88 and 89 under 35 U.S.C. §103(a) as being unpatentable over Xu et al. as applied to claims 1, 4, 68, 81 and 88 above, and further in view of Kumar, U.S. Patent No. 5,916,776 and Buck et al., *BioTechniques* 27: 528-36, 1999. The Examiner has indicated that Xu et al. teach the making and use of probes and primers for the

detection of an identified gene (PMEPA1), some of such primers, according to the Examiner, being 20 and 22 bases that hybridize to SEQ ID NO: 3 or its complement (and, therefore, SEQ ID NO: 1 or its complement). The Examiner further argues that Kumar teaches that probes and primers may comprise anywhere from 15 to 500 nucleotides. The Examiner maintains that it would have been obvious to use primers of any of these lengths that comprise the sequence of the gene disclosed by Xu et al. Additionally, the Examiner argues that Buck et al. teach that the sequence of a primer or probe is not important, and, therefore, concludes that one of ordinary skill in the art would expect that any primer or probe would be effective.

Applicant respectfully traverses the rejection. Applicant wishes to note that the sequence of the gene identified by Xu et al. is not completely identical to the sequence provided in SEQ ID NOs: 1 or 3 of Applicant's invention. It is a portion of the nucleic acid sequence provided by Xu et al. that happens to have the same sequence as a portion of MIVR-1 provided by Applicant. Therefore, even if *arguendo*, Xu et al. teach the making and use of primers for the detection of the sequence of PMEPA1, there is no guidance provided by Xu et al. alone or in combination with the other references cited by the Examiner to direct one of ordinary skill in the art to design primers or probes to the portion of the Xu et al. sequence that has identity to a portion of the gene identified by Applicant, MIVR-1. At best, even if the references cited by the Examiner lead one of ordinary skill in the art to make primers or probes to detect PMEPA1, which Applicant does not concede that they do, these primers and probes would not necessarily be the nucleic acids of Applicant's claims. Additionally, as one of ordinary skill in the art is not directed to focus on the portion of PMEPA1 that is identical to the portion of MIVR-1, there is no expectation of success in the creation of a nucleic acid encompassed by Applicant's claims. Furthermore, Applicant also notes that there is no motivation provided by the references to suggest that one of ordinary skill in the art would even go beyond the probes and primers of Xu et al.

In order to demonstrate a *prima facie* case of obviousness, it is necessary for the Examiner to demonstrate that one of ordinary skill in the art would be motivated to combine the teachings of the cited references, that the compositions of Applicant's claims would be the result and that there is an expectation of success to achieve this result. Applicant maintains that this has not been demonstrated. There are no teachings to indicate that the probes and primers, if produced as the Examiner has argued, would necessarily be directed to the portion of the Xu et

al. sequence that happens to correspond to a portion of the MIVR-1 sequence. There are also no teachings to establish the expectation of success in necessarily producing a nucleic acid as encompassed by Applicant's claims or the motivation to make and use probes and primers other than those provided by Xu et al.

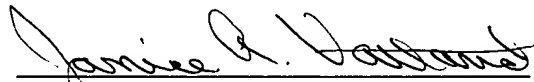
Accordingly, withdrawal of this rejection is respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, this application should now be in condition for allowance. A notice to this effect is respectfully requested. If the Examiner believes, after this amendment, that the application is not in condition for allowance, the Examiner is requested to call the Applicant's representative at the telephone number listed below.

If this response is not considered timely filed and if a request for an extension of time is otherwise absent, Applicant hereby requests any necessary extension of time. If there is a fee occasioned by this response, including an extension fee, that is not covered by an enclosed check, please charge any deficiency to Deposit Account No. 23/2825.

Respectfully submitted,



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